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## Prevention

### THE EFFECT OF STATINS ON SKELETAL MUSCLE FUNCTION

ACC Oral Contributions

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**Background:** Hydroxy-methylglutaryl (HMG) CoA reductase inhibitors or statins are the most effective medications for reducing elevated concentrations of low-density lipoprotein cholesterol (LDL-C). Many clinicians believe that statins increase muscle pain, but this has not been observed in controlled clinical trials and the effect of statins on muscle performance has not been carefully examined.

**Methods:** The Effect of Statins On Skeletal Muscle Function and Performance (STOMP; NCT00609063) study administered atorvastatin 80 mg daily (ATOR: n=202 with 103 women; age  $43 \pm 16$  yrs) or placebo (PL: n=217 with 113 women; age  $45 \pm 16$  yrs) to healthy, statin-naïve subjects for 6 months or until subjects met the study definition of myalgia (new and unexplained muscle pain on study drug that abated with dechallenge and reoccurred upon rechallenge). Blood lipids, creatine kinase (CK), alanine aminotransferase (ALT), and muscle strength (handgrip, elbow and knee isometric and isokinetic strength, knee endurance) were measured at baseline and again after completing drug treatment.

**Results:** Compliance to drug treatment did not differ ( $p = 0.44$ ) between groups (ATOR:  $94.5 \pm 7.0\%$  vs. PL:  $93.9 \pm 8.2\%$  compliance). LDL-C decreased ( $p < 0.01$ ) by  $59.1 \pm 31.7$  mg/dL in ATOR subjects with no change in PL subjects. CK and ALT increased (both  $p < 0.01$ ) in ATOR subjects by  $20.8 \pm 141.1$  and  $15.7 \pm 27.5$  U/L, respectively, with no change in PL subjects ( $\Delta$ CK:  $1.5 \pm 167.6$  U/L and  $\Delta$ ALT:  $3.2 \pm 24.3$  U/L). There were no significant changes in muscle strength or aerobic performance with ATOR vs. PL (all  $p > 0.19$ ). Nineteen ATOR subjects and 10 PL subjects met the study definition for myalgia ( $X^2 = 3.74$ ;  $p = 0.05$ ). The myalgic ATOR subjects exhibited muscle strength declines in 10 of 16 measured variables whereas the myalgic PL subjects exhibited strength declines in 4 of 16 variables ( $X^2 = 4.6$ ;  $p = 0.03$ ).

**Conclusion:** These results from a blinded controlled trial confirm the clinical impression that statins increase muscle symptoms in previously untreated subjects. Moreover, statin-associated myalgia appears to induce skeletal muscle strength declines that could exacerbate existing disease pathologies and compromise quality of life.